

# **EXHIBIT E**



HSP Case Identification		FORM 01	
CASE ADDRESS	NAME		
	STREET	706	
	CITY	OHIO 45223	ZIP
	WORKDAY PHONE(S)		
	HOME/EVENING PHONE(S)	(513) 541-1	
PROXY	NAME	4	
	STREET	(SAME)	
	CITY	ZIP	
	RELATIONSHIP TO CASE	POLICE	
	WORKDAY PHONE(S)		
	HOME/EVENING PHONE(S)	(513) 541-1	
CONTACT #1	NAME	NONE	
	STREET		
	CITY	ZIP	
	RELATIONSHIP TO CASE		
	WORKDAY PHONE(S)		
	HOME/EVENING PHONE(S)		
CONTACT #2	NAME	NONE	
	STREET		
	CITY	ZIP	
	RELATIONSHIP TO CASE		
	WORKDAY PHONE(S)		
	HOME/EVENING PHONE(S)		
Notes:			
INTERVIEWS:			
CASE	02113198	REASON INTERVIEW NOT COMPLETED	STAFF/REASON
PROXY	02114198		13031
CTLA	02112198		13031
CTLB	02111198		13101
			13101

## HS- Event Evaluation

FORM 02

CASE STUDY NUMBER

330080

FIRST 3 LETTERS OF LAST NAME

## A. DESCRIPTION OF NEUROLOGIC EVENT

## 1. INITIAL SYMPTOMS

Source of data:

Med. record ☒Doctor ☐Nurse ☐

HUSBAND'S RECORDS INDICATE NO SIGNIFICANT PAST

MEDICAL HISTORY FOUND BY HUSBAND ON

7:00 AM

JULY 98 ONE HOUR AFTER LEAVING FOR WORK AT 6:00 AM

SLUMPED OVER IN SEAT OF VAN, RESTRAINED

RESPONDING BUT NOT COHERENT, NOT VERBALIZING

(MINOR DAMAGE TO VAN)

	Yes	No	NM
Headache	1	2	3
Nausea	1	2	3
Vomiting	1	2	3
Left-sided weakness	1	2	3
Right-sided weakness	1	2	3
Memory problems/confusion	1	2	3
Change in double vision	1	2	3
Other	1	2	3

Date &  
Time  
of01/15/98  
month day yearSymptom  
Onset06:00 am  
hour min pm 2

## 2. PRECIPITATING ACTIVITIES

Source of data:

Med. record ☒Doctor ☐Nurse ☐

DRIVING TO WORK

	Yes	No	NM
Sexual activity	1	2	3
Defecation/micturition	1	2	3
Exercise/other effortful activity	1	2	3
Strong emotion/arguing	1	2	3
Sleeping/eating/sitting	1	2	3
Other	1	2	3

## 3. ACTIONS TAKEN

Source of data:

Med. record ☒Doctor ☐Nurse ☐

HUSBAND CALLED LIFE SQUAD TAKEN TO GOOD

SAMARITAN CTR RT TEMPORAL LOBE HEM.

P.S.A.H. 6 MASS P220Z SLIGHT RT 7.17 SH. 27

SM ET RIM SDH ANGIOLOGIC - 12MM TRILUBED

ANGIOLOGIC OF THE RT MCA TRI 7.17-12.00

Date &  
Time  
of01/15/98  
month day yearArrival  
at ER08:15 am  
hour min pm 2

Staff completing section / Date completed

ENTERED JUL 01 1998

503

01/17/98  
month day year

(Rev 022296)

CHECKED JUL 15 1998

EDITED

ENTERED

**B. DIAGNOSTIC STUDIES****Head Imaging Study**

Done 1 Not done 2

1. Type of study [ENTER DATA FOR STUDY THAT FIRST SHOWED EVIDENCE OF HEMORRHAGE] CT 1 MRI 2 MRI/MRA 3 Without contrast 1 With contrast 2 With & without contrast 3
2. Date and time of study Location study performed: Good Samaritan 01/15/98 month day year 8:58 hour 58 min 1 am 2 pm
3. Findings:
- |                             | Yes | No | Unc |
|-----------------------------|-----|----|-----|
| Intraparenchymal hemorrhage | 1   | 2  | 8   |
| Subarachnoid hemorrhage     | 1   | 2  | 8   |
| AVM                         | 1   | 2  | 8   |
| Aneurysm                    | 1   | 2  | 8   |
| Tumor                       | 1   | 2  | 8   |
| Ischemic                    | 1   | 2  | 8   |
| Other                       | 1   | 2  | 8   |

**Lumbar Puncture**

Done 1 Not done 2

1. Date and time of study month day year hour min am pm
2. Red blood count Tube #1 mm3 Tube #2 mm3
3. Xanthochromasia present Yes 1 No 2 Unc 3 4. Opening pressure mmH2O

**Angiogram**

Done 1 Not done 2

1. Type of Study 4-vessel 1 3-vessel 3 2-vessel 2 1-vessel 1
2. Date and time of study Location study performed: Good Samaritan 01/15/98 month day year 08:12 hour 12 min 1 am 2 pm
3. Findings:
- |          | Yes | No | Unc |
|----------|-----|----|-----|
| Normal   | 1   | 2  | 8   |
| AVM      | 1   | 2  | 8   |
| Aneurysm | 1   | 2  | 8   |
| Tumor    | 1   | 2  | 8   |
| Thrombus | 1   | 2  | 8   |
| Spasm    | 1   | 2  | 8   |
| Other    | 1   | 2  | 8   |

Staff completing section / Date completed

SC3 01/27/98 month day year**C. DIAGNOSTIC IMPRESSION**

[CHECK DOCUMENTS AVAILABLE AT TIME SECTION COMPLETED]

Admission notes ☒ Head CT report ☒ Angiogram ☒  
 Discharge summary ☐ MRI report ☐ LP Results ☐  
 Form 02c ☐

**Eligibility of Event**

1. Event type IF OTHER, DESCRIBE: Hemorrhagic stroke 1 Non-hemorrhagic stroke 2 Other 3 Uncertain 8
2. Cause of hemorrhage IF OTHER, SPECIFY: Tumor 01 Blood dyscrasias 05 Other 09  
 Vasculitis 02 Aneurysm 06 Uncertain 88  
 AVM 03 Anticoagulants 07 NA 99  
 Cavernous malformation 04 Thrombolytic agents 08

**Determination of Index Date/Focal Time**

1. Index Date/Focal Time 1 [ONSET OF SIGNS LEADING TO DIAGNOSIS] 01/15/98 06:00 hour min 1 am 2 pm 8 DK
2. SENTINEL SYMPTOMS: Present 1 Absent 2 Unknown 8 [ONSET OF SENTINEL SYMPTOMS] 1 1 1 hour min 1 am 2 pm 8 DK

Staff completing section / Date completed

SC1 01/27/98 month day year



**HSP Event Evaluation (from subject) FORM 02c**CASE STUDY NUMBER 350080

FIRST 3 LETTERS OF LAST NAME

DATE FORM 02 COMPLETED 02/13/98PERSON COMPLETING FORM SC**A. DESCRIPTION OF NEUROLOGIC EVENT**

1. SYMPTOMS: Can you describe the symptoms that brought you to the hospital?  
When did you FIRST begin to feel these symptoms?

CASE DOESN'T REMEMBER FEELING ILL ON  
01/15/98 LEFT FOR WORK AT 6:00 AM  
WAS SMOKING A CIGARETTE & DRINKING COFFEE  
AT TIME THAT'S LAST THING THE CASE  
REMEMBER  
PROXY STATED THAT THE CASE HAD  
NOT COMPLAINED OF FEELING ILL  
ON 1/15/98 APPROX 45 MINS AFTER

	Yes	No	Unc
Headache	1	2	8
Nausea	1	2	8
Vomiting	1	2	8
Left-sided weakness	1	2	8
Right-sided weakness	1	2	8
Memory problems/confusion	1	2	8
Change in double vision	1	2	8
Other	3	2	8

Date & Time of Symptom Onset  
01/15/98  
month day year  
06:00 am  
hr min pm

THE CASE HAD LEFT FOR WORK HE FOUND HER UNINRESPONSIVE  
& SLIGHT DAMAGE CASE WAS RESTRAINED BY SEAT BELTS  
& UNRESPONSIVE

2. PRECIPITATING ACTIVITIES: What were you doing at the time you FIRST felt the symptoms that brought you to the hospital?

DRIVING TO WORK

	Yes	No	Unc
Sexual activity	1	2	8
Defecation/micturition	1	2	8
Exercise/other effortful activity	1	2	8
Strong emotion/arguing	1	2	8
Sleeping/feeling drowsy	1	2	8
Other	1	2	8

3. ACTIONS TAKEN What did you do in response to these symptoms?  
When did you FIRST go to a hospital for these symptoms?

CASE DOESN'T REMEMBER PROXY STATES  
HE CALLED 1-911 (POLICE) & CASE WAS TAKEN  
TO GOOD SAMARITAN

Date & Time of Arrival at ER  
01/15/98  
month day year  
07:59 am  
hr min pm

**COGNITIVE EVALUATION** [Complete Section B before administering interview (Form 04)]

Now, I have a few quick questions to check your level of alertness.

First, I have 2 'yes/no' questions.

Q1 Can you tell me, [Yes or No], as part of this study, have we asked you to take a pill?

Q2 As part of this study, have we asked you to answer a series of questions?

Q3 What is the current month?

Q5 Please, close and open your eyes.

Q7 Level of consciousness:

Q4 How old are you?

Q6 Please, close and open you hand.

Alert; drowsy; stuporous; coma

Q1 Y/N

Q2 D/N

Q3 Feb.

Q4 34

Q5 D/N

Q6 D/N

Q7 Alert

0 2 1 3 1 9 8

Acceptable 1

Not acceptable 2

Check if able to interview ☒

Q1 Y/N

Q2 Y/N

Q3

Q4

Q5 Y/N

Q6 Y/N

Q7

Acceptable 1

Not acceptable 2

Check if able to interview ☐

Q1 Y/N

Q2 Y/N

Q3

Q4

Q5 Y/N

Q6 Y/N

Q7

Acceptable 1

Not acceptable 2

Check if able to interview ☐

Q1 Y/N

Q2 Y/N

Q3

Q4

Q5 Y/N

Q6 Y/N

Q7

Acceptable 1

Not acceptable 2

Check if able to interview ☐

Q1 Y/N

Q2 Y/N

Q3

Q4

Q5 Y/N

Q6 Y/N

Q7

Acceptable 1

Not acceptable 2

Check if able to interview ☐

Comments:

**Proxy Respondent**

As a separate study we are also examining the usefulness of indirect - or Proxy - interviews for medical research. We would like to ask a person who knows you well some of the same questions as we ask you. We will then compare their responses with yours to see how useful these 'proxy' interviews are in providing information. We would like to speak with the person who knows best how you felt and what medications, if any, you may have taken in the two weeks before your admission. Would it be possible for us to speak with that person and ask them if they would be willing to be interviewed?

No ☐

Yes ☒

[IF YES, RECORD PROXY INFORMATION ON FORM 01.]

**A. ILLNESS SYMPTOMS AND MEDICATION USE**

1. First, I would like to ask you about some common illness symptoms.

FOR EACH SYMPTOM, ASK: Do you recall having a [SYMPTOM] at any time during this 2-week period?  
[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

IF NO, RECORD BELOW AND SKIP TO NEXT SYMPTOM.

IF YES OR DK, RECORD BELOW AND PROBE:

Did you have this [SYMPTOM] on [ID]?

Did you have this [SYMPTOM] at any time in the three days before [ID]?

Did you have this [SYMPTOM] at any OTHER time during this 2-week period?

Did you use any medication to treat this symptom during this period? [IF YES, PROBE FOR AND RECORD MED(S).]

SYMPTOM	SYMPTOM PRESENT?	DAYS PRESENT			MED. USED?	Medications used for symptom
	ID	-1-2-3	Other days			
	(1=YES; 2=NO; 7=REF; 8=DK)					
a. Cough	<u>2</u> (5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Runny nose	<u>2</u> (10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Nasal congestion	<u>2</u> (15)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Sore throat	<u>2</u> (20)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Headache	<u>2</u> (25)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

[RECORD MEDICATION NAMES IN SECTION B.]

f. IF ANY SYMPTOMS REPORTED IN [a-d], PROBE:

Do you believe your symptom[s] was[were] caused by a respiratory infection (such as a cold or flu) or were due to allergies?

Infection 1 Ref 7 (30)  
Allergies 2 DK 8  
Neither/other 3

2. Now, I would like you to try to recall ANY [other] MEDICATIONS you may have used during this time period.  
[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

Please look at the calendar again and take a minute to think about ANY [other] medication or drug you may have taken ON THE ID, IN THE THREE DAYS BEFORE THAT DATE, OR AT ANY OTHER TIME DURING THESE TWO WEEKS. We are interested in ANY medication that you may have taken, including those prescribed by a doctor OR that you bought over-the-counter.

Note names of medications recalled below:

[Other] medication recalled 1 None recalled 2 DK 8 (31)

[RECORD MEDICATION NAMES IN SECTION B.]



**A. ILLNESS SYMPTOMS AND MEDICATION USE, continued**

3. I would now like to review some SPECIFIC MEDICATIONS you may have taken during this period of time.

[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

Did you take...

**TAKEN**

[1= YES; 2=NO;

7=REF; 8=DK]

If medication taken, note names below:

- a. Aspirin?
- b. Acetaminophen [such as Tylenol]?
- c. Anti-inflammatories [such as Advil, Motrin, Naprosyn, or Feldene]?
- d. Blood thinners [such as Coumadin]?
- e. Asthma medication [e.g., an inhaler, Theophylline, or Prednisone]?
- f. Medication for depression [such as Marplan, Nardil, or Parlate]?
- g. Hemorrhoidal preparations?

2

2

2

2

2

2

2

(32)

[RECORD MEDICATION NAMES IN SECTION B.]

4. I would now like to ask you about some OTHER DRUGS you may have used during this time.

[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

As with all your answers during this interview, your responses to these questions regarding drug use are confidential and please remember that your frank answers are very important for this research.

Please look at this table [SHOW CARD] and try to remember if you used any of these drugs during this period.

I will point to each drug.

Did you use ...

**TAKEN**

[1= YES; 2=NO;

7=REF; 8=DK]

If drug taken, note names below:

- a. Marijuana
- b. Hashish
- c. Cocaine/Crack
- d. Speed
- e. LSD
- f. Ecstasy
- g. Heroin
- h. Methadone
- i. ICE
- j. PCP
- k. Inhalents
- l. Other

2

2

2

2

2

2

2

2

2

2

2

2

(33)

[RECORD DRUG NAMES IN SECTION B.]

**RECORD DETAILS OF MEDICATION/DRUG USE IN SECTION B1.**

5. FOR CASE: Did you take any medication between the time your symptoms began on [ID] [i.e., Focal Time] and the time you were admitted to the hospital?

Note names of medications recalled below:

Medication recalled 1

None recalled 2

DK 8

NA 9

(51)

**RECORD DETAILS OF MEDICATION/DRUG USE IN SECTION B2.**

**C. CAFFEINE USE**

Now, I'd like to ask a few questions about your consumption of coffee and other beverages containing caffeine. We are only interested in drinks that contain caffeine. Please, do not include decaffeinated beverages in your answers.

FOR EACH DRINK TYPE:

cups of coffee  
cups of tea,  
caffeinated sodas

REPEAT QUESTIONS IN BOXED AREA.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Do you ever drink [DRINK TYPE]?

On [DAY] how many [DRINK TYPE] did you have?  
\*(If ID, probe for use before Focal Time)

What was your average DAILY consumption of [DRINK TYPE] in the last 6 months?

DRINK TYPE	Never Used	ID*	-1	-2	-3	Average daily consumption
1. Cups of coffee	<input type="checkbox"/>	0 2 0 (9)	0 4 0 (8)	0 4 0 (11)	0 4 0 (14)	0 4 0 8 oz. cups (17)
2. Cups of tea (including iced tea)	<input checked="" type="checkbox"/>	— — — (20)	— — — (23)	— — — (26)	— — — (29)	— — — 8 oz. cups (32)
3. Caffeinated sodas (e.g., Coke, Pepsi, Mountain Dew)	<input checked="" type="checkbox"/>	— — — (35)	— — — (38)	— — — (41)	— — — (44)	— — — 12 oz. sodas (47)

IF CAFFEINATED BEVERAGES CONSUMED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, your last caffeine-containing beverage was on day [SPECIFY DAY].

On that day, at what time of day did you have your LAST drink containing caffeine? 05:59 am 1 (50)  
Time of day pm 2  
dk 8

4. Did you take any caffeine-containing stimulants (such as No-Doz or Vivarin) on ID or in the 2 weeks before ID?

Yes 1 No 2 Ref 7 DK 8

(52)

**D. ALCOHOL USE**

Now, I'd like to ask a few questions about your use of alcohol.

1. The first few questions cover your past, as well as current, use of alcohol.

- a. Have you ever felt that you ought to cut down on your drinking?  
b. Have people annoyed you by criticizing your drinking?  
c. Have you ever felt bad or guilty about your drinking?  
d. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?

Yes	No	Ref	DK
1	2	7	8
1	2	7	8
1	2	7	8

(5)

2. In the last 6 months, have you consumed any alcoholic beverages (that includes beer, wine, mixed drinks and liquors)?

Yes 1  
No 2  
Ref 7  
DK 8

(9)

SKIP TO E

FOR EACH DRINK TYPE:

glasses of wine  
bottles or cans of beer,  
mixed drinks or liquors

REPEAT QUESTIONS IN BOXED AREA.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Do you ever drink [DRINK TYPE]?

On [DAY] how many [DRINK TYPE] did you have?  
\*(If ID, probe for use before Focal Time)

What was your average WEEKLY consumption of [DRINK TYPE] in the last 6 months?

DRINK TYPE	Never Used	ID*	-1	-2	-3	Average weekly consumption
a. Glasses of wine	<input type="checkbox"/>	— — — (10)	— — — (13)	— — — (16)	— — — (19)	— — — 4 oz. glasses (22)
b. Bottles/cans of beer	<input type="checkbox"/>	— — — (25)	— — — (28)	— — — (31)	— — — (34)	— — — 12 oz. bottles (37)
c. Mixed drinks/liquors	<input type="checkbox"/>	— — — (40)	— — — (43)	— — — (46)	— — — (49)	— — — drinks (1oz. liquor) (52)

IF ALCOHOL CONSUMED ON ID, -1, -2, OR -3, PROBE:

d. During this 4-day period, your last alcohol-containing drink was on day [SPECIFY DAY].  
On that day, at what time of day did you have your LAST drink containing alcohol?

Time of day am 1 (55)  
pm 2  
dk 8

## 1. TOBACCO USE

1. Have you ever smoked cigarettes?

Yes ①

(5)

No 2

Ref 7

DK 8

SKIP TO 2 &lt;

a. At what age did you first start smoking cigarettes?

14

(6)

b. Do you still smoke cigarettes?

SKIP TO c &lt; Yes ①

Ref 7

(8)

No 2

DK 8

IF NO, PROBE:

How long has it been since you last smoked?

\_\_\_\_ yrs. (9)

During the years you smoked,

how many cigarettes would you say you smoked in an average day?

\_\_\_\_ cgs. (12)

SKIP TO d.

c.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Can you tell me, on [DAY] how many cigarettes did you smoke?\*

\*If ID, probe for use before Focal Time]

How many cigarettes would you say you normally smoked in an average day over the last 6 months?

	ID*	-1	-2	-3	Avg. daily cigarettes
Cigarettes	020 (15)	300 (18)	500 (21)	300 (24)	300 cigarettes (27)

IF CIGARETTES USED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, your last cigarette was on day [SPECIFY DAY].

On that day, at what time of day did you have your LAST cigarette?

05:59	am	①	(30)
Time of day	pm	2	
	dk	8	

d. Did you use any nicotine patches (such as Nicoderm) or nicotine gum (such as Nicorette) on ID or in the 2 weeks before ID?

Yes 1 No ② Ref 7 DK 8 (35)

2. Have you ever smoked cigars?

Yes 1

(36)

No ②

Ref 7

DK 8

SKIP TO 3 &lt;

a. At what age did you first start smoking cigars?

(37)

b. Do you still smoke cigars?

SKIP TO c &lt; Yes 1

Ref 7

(39)

No 2

DK 8

IF NO, PROBE:

How long has it been since you last smoked?

\_\_\_\_ yrs. (40)

During the years you smoked:

How many cigars would you say you smoked in an average day?

\_\_\_\_ cgs. (43)

SKIP TO 3.

c.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Can you tell me, on [DAY] how many cigars did you smoke?\*

\*If ID, probe for use before Focal Time]

How many cigars would you say you normally smoked in an average day over the last 6 months?

	ID*	-1	-2	-3	Avg. daily cigars
Cigars	____ (46)	____ (49)	____ (52)	____ (55)	____ cigars (58)

IF CIGARS USED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, your last cigar was on day [SPECIFY DAY].

On that day, at what time of day did you have your LAST cigar?

____	am	1	(61)
Time of day	pm	2	
	dk	8	

## 2. MEDICAL HISTORY, continued

6. Have you ever been told by a doctor that you had diabetes or high blood sugar?

Yes	1
No	2
Ref	7
DK	8

SKIP TO 7&lt;

a. How old were you when you were FIRST told you were diabetic or had high blood sugar?

IF CASE AND AGE FIRST TOLD IS WITHIN 1 YEAR OF CURRENT AGE, PROBE:  
Was this before or after your hospital admission on [ADM. DATE]?

Before 1 After 2 DK 8

b. Are you taking any medication for this condition?

Yes	1
No	2
Ref	7
DK	8

SKIP TO 7&lt;

Are you being treated with...

Yes No DK

IF YES, YEAR TREATED BEGAN

Insulin injections?

1 2 8

Pills (e.g., Diabinese, Orinase,

Glucotrol, Micronase, Gliburide)?

1 2 8

If pills, specify name: \_\_\_\_\_

7. Have you ever been told by a doctor that you had thyroid disease?

IF YES, PROBE: Was it called hypo- or hyper-thyroidism?

Yes	1
No	2
Hypothyroidism	3
Hyperthyroidism	4
Uncertain type	5
DK	8

SKIP TO 8&lt;

a. Did you ever require any of the following medications...

Yes No Ref DK

Radioactive iodine?

1 2 7 8

Tapazole or PTU?

1 2 7 8

Synthroid or thyroxine?

1 2 7 8

Other?

1 2 7 8

SPECIFY: \_\_\_\_\_

8. [BEFORE [ID], HAD] Have you ever been told by a doctor that you had any of the following conditions?

Yes No Ref DK

a. Cancer? IF YES, SPECIFY TYPE(S): \_\_\_\_\_

1 2 7 8

b. Lung disease (e.g., bronchial asthma, emphysema, COPD)?

1 2 7 8

c. Kidney failure or insufficiency?

1 2 7 8

d. Polycystic kidney disease?

1 2 7 8

e. Cirrhosis of the liver?

1 2 7 8

f. Other chronic liver disease?

1 2 7 8

g. Elevated cholesterol or blood lipids?

1 2 7 8

h. Sickle cell anemia?

1 2 7 8

i. Hemophilia?

1 2 7 8

j. Other bleeding or clotting disorders (such as Von Willebrand's disease)?

1 2 7 8

9. Have you ever had any episodes of prolonged or heavy bleeding [e.g., heavy bleeding after a tooth extraction or after a cut to your skin]?

1 2 7 8

10. Before [ID], did you ever suffer from migraine headaches?

1 2 7 8

IF NO, SKIP TO J.

IF YES, ASK: Has a doctor ever told you that you had migraine headaches?

1 2 7 8

## K. SES INFORMATION

Finally, I have a few general questions.

1. To what ethnic or racial group do you belong? Indian (Am.)/Alaskan native 05 Ref 77 (15)  
Asian/Pacific Islander 06 DK 88  
Other 07
- White, not of hispanic origin 01  
White, of hispanic origin 02  
Black, not of hispanic origin 03  
Black, of hispanic origin 04
2. Are you currently married or living with a partner?  
IF UNMARRIED, PROBE: Have you ever been married? Never married 1 Divorced 5 (17)  
Married 2 Separated 6  
Living with partner 3 Ref 7  
Widowed 4 DK 8
3. a. What was the highest grade of schooling that you completed? Highest grade 1 2 (16)  
Ref 7 7  
DK 8 8  
No formal education=00  
College=13 14 15 16 17  
Elementary school=1 2 3 4 5 6 7 8  
Post-college: \_\_\_\_\_  
High school=9 10 11 12
- b. IF SUBJECT IS CURRENTLY MARRIED/or living with partner (OR HAS BEEN MARRIED), ASK: Highest grade 1 1 (10)  
Ref 7 7  
DK 8 8  
What was the highest grade of schooling your spouse/partner (former spouse) completed?
4. a. Are you currently employed outside of the home?  
IF NO, PROBE: Have you ever worked outside the home? Currently employed 1 (12)  
Formerly employed 2  
Never employed 3  
Ref 7  
DK 8
- IF CURRENTLY [FORMERLY] EMPLOYED, PROBE:  
What work do [did] you do [in your last place of employment]? 0043 (13)  
FACTORY WORKING
- b. IF SUBJECT IS CURRENTLY MARRIED/or living with partner (OR HAS BEEN MARRIED), ASK: 0083 (17)  
What work does (did) your spouse/partner (former spouse) do in her/his last place of employment?  
FACTORY SHIPPING
5. Are you currently covered by any medical insurance? Yes 1 (21)  
No 2  
Ref 7  
DK 8
- SKIP TO 6 ←
- a. What type of insurance do you have? Medicare 1 Other private 4 (22)  
Medicaid 2 Ref 7  
HMO 3 DK 8
6. Please look at this table (SHOW CARD) Using the letters shown (A - X) can you tell me which letter corresponds to your (and your spouse/partner's) income for the past year? Code \_\_\_\_\_ (23)  
Ref 7  
DK 8  
Include income from all sources such as wages, salaries, government assistance, help from relatives, rent from property, etc.
7. What is your zipcode (at home)? 45223 (24)
8. May we have your full home address for purposes of a possible follow-up study?  
[RECORD ON FORM 01.]

That is the end of the interview. Thank you very much for your answers."

INTERVIEW COMPLETED

END OF INTERVIEW

\*Verify medications.



## L. INTERVIEWER OBSERVATIONS

(PLEASE COMPLETE IMMEDIATELY FOLLOWING INTERVIEW.)

## 1. Aphasia severity rating

~~(BASES ONLY)~~

No usable speech or auditory comprehension

7

(8)

All communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. The range of information that can be exchanged is limited, and the listener carries the burden of communication.

6

Conversation about familiar subjects is possible with help from the listener. There are frequent failures to convey the idea, but patient shares the burden of communication with the examiner.

5

The patient can discuss almost all everyday problems with little or no assistance. Reduction of speech and/or comprehension, however, makes conversation about certain material difficult or impossible.

4

Some obvious loss of fluency in speech or facility or comprehension, without significant limitation on ideas expressed or form of expression.

3

Minimal discernible speech handicaps; patient may have subjective difficulties that aren't apparent to listener.

2

No deficits

1

## 2. Language ability of subject during interview:

No language problem

1

(6)

Has some difficulty speaking English

2

Has great difficulty speaking English

3

## 3. Language spoken by subject during interview:

English

1

(7)

Spanish

2

Portuguese

3

Italian

4

SPECIFY:

Other

5

## 4. Rate your confidence in the ability of the subject to give an accurate history:

Very confident

1

(9)

Fairly confident

2

Confident

3

Somewhat confident

4

Little or no confidence

5

## 5. Was anyone else present during the interview?

No

1

(9)

Spouse

2

Child

3

Other relative

4

Friend

5

Neighbor

6

SPECIFY:

Other

7

IF YES: How long were they present?

Entire interview

1

(10)

During first half only [i.e., sections A,B]

2

During second half only

3

## 6. Was the interview completed?

Yes; Interview completed with little (&lt;1/10) or no missing information

1

(11)

Yes; Interview completed with considerable amount (&gt;1/10) of missing information

2

No: Interview terminated before completion

3

IF INTERVIEW NOT COMPLETED: When did interview end?

Last page completed

(12)

Last question completed

(14)

## 7. Where was the interview conducted?

Hospital

Rehab. Center

2

Subject's home

3

Subject's office

4

(18)

IF OTHER, SPECIFY:

Friend/neighbor home

5

Other

6

## Proxy Case Interview

FORM 04p

STUDY NUMBER 350080P  
~~33-00377~~  
 (15)

DATE OF INTERVIEW 02/14/98  
 (15)

TIME INTERVIEW STARTED 12:05 AM 1 PM 2  
 (24)

FIRST 3 LETTERS OF LAST NAME ---  
 (12)

PERSON COMPLETING FORM 303  
305  
 (21)

## REVIEW OF INDEX DATE AND PRECEDING TIME PERIOD

During this interview, we would like to focus on [CASE NAME] experiences in a specific period of time; that is, the day 02/13/98 [ID], and the TWO WEEKS before that day. (22)

01 index date 78

To help you remember, we will be using this calendar. (DISPLAY CALENDAR)

I will circle the index date, which was a [DAY OF WEEK] and note the time of day that [CASE NAME] started to have symptoms 06:00 (any pm) and the time of day when [HE/SHE] arrived at the hospital 02:52 (any pm). (NOTE ON CALENDAR DATE OF HOSPITAL ARRIVAL, IF DIFFERENT FROM INDEX DATE.)

I would like you to try to remember that day [ID] and the 2 weeks before that day. (HIGHLIGHT DAYS ON CALENDAR)

Was there a trip, birthday or other special occasion during that time period that would help you to remember?  
 (MARK ALL BIRTHDAYS, SPECIAL OCCASIONS, ETC. ON CALENDAR)

Before we begin, we would like you to know that your responses to these questions will be completely confidential. We have received a Certificate of Confidentiality from the Department of Health and Human Services. This certificate protects medical investigators from being forced to release data in which a research subject may be identified. Researchers are allowed to reveal your identifying information only if you consent in writing to its disclosure. When results of this study are published, neither your name or [CASE]'s name will be used.

Neither your name or [CASE]'s name will be attached to this interview form.  
 Please remember that your frank answers are critically important for this research.

**A. ILLNESS SYMPTOMS AND MEDICATION USE**

1. First, I would like to ask you about some common illness symptoms.

FOR EACH SYMPTOM, ASK: Do you recall [CASE NAME] having a [SYMPTOM] at any time during this 2-week period?  
[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

IF NO, RECORD BELOW AND SKIP TO NEXT SYMPTOM.

IF YES OR DK, RECORD BELOW AND PROBE:

Did [HE/SHE] have this [SYMPTOM] on [ID]?

Did [HE/SHE] have this [SYMPTOM] at any time in the three days before [ID]?

Did [HE/SHE] have this [SYMPTOM] at any OTHER time during this 2-week period?

Did [HE/SHE] use any medication to treat this symptom during this period? [IF YES, PROBE FOR & RECORD MED(S).]

SYMPTOM	SYMPTOM PRESENT?	DAYS PRESENT			MED. USED?	Medications used for symptom
		ID	-1,-2,-3	Other days		
a. Cough	<input checked="" type="checkbox"/> (5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Runny nose	<input checked="" type="checkbox"/> (10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Nasal congestion	<input checked="" type="checkbox"/> (15)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Sore throat	<input checked="" type="checkbox"/> (20)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Headache	<input checked="" type="checkbox"/> (25)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

[RECORD MEDICATION NAMES IN SECTION B.]

i. IF ANY SYMPTOMS REPORTED IN [a-d], PROBE:

Do you believe [HIS/HER] symptom[s] was[were] caused by a respiratory infection (such as a cold or flu) or were due to allergies?

Infection 1 Ref 7 (30)  
Allergies 2 DK 8  
Neither/other 3

2. Now, I would like you to try to recall ANY [other] MEDICATIONS [CASE NAME] may have used during this time period.

[INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

Please look at the calendar again and take a minute to think about ANY [other] medication or drug [HE/SHE] may have taken ON THE ID, IN THE THREE DAYS BEFORE THAT DATE, OR AT ANY OTHER TIME DURING THESE TWO WEEKS.

We are interested in ANY medication that [CASE NAME] may have taken, including those prescribed by a doctor OR those [HE/SHE] bought over-the-counter.

Note names of medications recalled below:

[Other] medication recalled 1 None recalled 2 DK 8 (31)

[RECORD MEDICATION NAMES IN SECTION B.]

Page 2

**A. ILLNESS SYMPTOMS AND MEDICATION USE, continued**

3. I would now like to review some SPECIFIC MEDICATIONS [CASE NAME] may have taken during this period of time.  
 [INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

Did [HE/SHE] take:

**TAKEN**

[1=YES; 2=NO;

7=REF; 8=DK] If medication taken, note names below:

- a. Aspirin?
- b. Acetaminophen (such as Tylenol)?
- c. Anti-inflammatories (such as Advil, Motrin, Napresyn, or Feldene)?
- d. Blood thinners (such as Coumadin)?
- e. Asthma medication (e.g., an inhaler, Theophylline, or Prednisone)?
- f. Medication for depression (such as Marplan, Nardil, or Parnate)?
- g. Hemorrhoidal preparations?

2

2

2

2

2

2

[RECORD MEDICATION NAMES IN SECTION B.]

4. I would now like to ask you about some OTHER DRUGS [CASE NAME] may have used during this time.  
 [INDICATE ID AND THE 2 WEEK PERIOD BEFORE ID ON CALENDAR.]

As with all your answers during this interview, your responses to these questions regarding drug use are confidential and please remember that your frank answers are very important for this research.

Please look at this table [SHOW CARD] and try to remember if [CASE NAME] used any of these drugs during this period.

I will point to each drug.

Did [HE/SHE] use ...

**TAKEN**

[1=YES; 2=NO;

7=REF; 8=DK] If drug taken, note names below:

- a. Marijuana
- b. Hashish
- c. Cocaine/Crack
- d. Speed
- e. LSD
- f. Ecstasy
- g. Heroin
- h. Methadone
- i. ICE
- j. PCP
- k. Inhalants
- l. Other

2

2

2

2

2

2

2

2

2

2

2

2

[RECORD DRUG NAMES IN SECTION B.]

**RECORD DETAILS OF MEDICATION/DRUG USE IN SECTION B1.**

5. Did [CASE NAME] take any medication between the time [HIS/HER] symptoms began on [ID] [i.e., Focal Time] and the time [HE/SHE] was admitted to the hospital?

Note names of medications recalled below:

Medication recalled 1

None recalled 2

DK 8

NA 9

(51)

**RECORD DETAILS OF MEDICATION/DRUG USE IN SECTION B2.**

**C. CAFFEINE USE**

Now, I'd like to ask a few questions about [CASE NAME'S] consumption of coffee and other beverages containing caffeine. We are only interested in drinks that contain caffeine. Please, do not include decaffeinated beverages in your answers.

FOR EACH DRINK TYPE: *cups of coffee*  
*cups of tea*  
*caffeinated sodas* REPEAT QUESTIONS IN BOXED AREA.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Does [CASE NAME] ever drink [DRINK TYPE]?

On [DAY] how many [DRINK TYPE] did  
[HE/SHE] have?  
\*[If ID, probe for use before Focal Time.]

What was [CASE NAME]'s average DAILY consumption of [DRINK TYPE] in the last 6 months?

DRINK TYPE	Never Used	ID*	-1	-2	-3	Average daily consumption
1. Cups of coffee	<input type="checkbox"/>	0 1 0 (5)	0 3 0 (8)	0 3 0 (11)	0 3 0 (14)	0 3 0 8 oz. cups (17)
2. Cups of tea (including iced tea)	<input checked="" type="checkbox"/>	— — — (20)	— — — (23)	— — — (26)	— — — (29)	— — — 8 oz. cups (32)
3. Caffeinated sodas (e.g., Coca, Pepsi, Mountain Dew)	<input type="checkbox"/>	0 0 0 (35)	0 2 0 (38)	0 2 0 (41)	0 2 0 (44)	0 2 0 12 oz. sodas (47)

IF CAFFEINATED BEVERAGES CONSUMED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, [HIS/HER] last caffeine-containing beverage was on day [SPECIFY DAY].  
On that day, at what time of day did [HE/SHE] have [HIS/HER] LAST drink containing  
caffeine?

05:52 am ① (50)  
Time of day pm 2  
dk 8

4. Did [HE/SHE] take any caffeine-containing stimulants (such as  
No-Doz or Vivarin) on ID or in the 2 weeks before ID? Yes 1 No ② Ref 7 DK 8 (55)

**D. ALCOHOL USE**

Now, I'd like to ask a few questions about [CASE NAME]'s use of alcohol.

1. The first few questions cover [HIS/HER] past, as well as current, use of alcohol.
- |   |     |    |     |    |     |
|---|-----|----|-----|----|-----|
|   | Yes | No | Ref | DK |     |
| a. Has [HE/SHE] ever felt that [HE/SHE] ought to cut down on [HIS/HER] drinking?                                    | 1   | ②  | 7   | 8  | (5) |
| b. Have people annoyed [HIM/HER] by criticizing [HIS/HER] drinking?   | 1   | ②  | 7   | 8  |     |
| c. Has [HE/SHE] ever felt bad or guilty about [HIS/HER] drinking?   | 1   | ②  | 7   | 8  |     |
| d. Has [HE/SHE] ever had a drink first thing in the morning to steady [HIS/HER] nerves or to get rid of a hangover? | 1   | ②  | 7   | 8  |     |
2. In the last 6 months, has [CASE NAME] consumed any alcoholic beverages (that includes beer, wine, mixed drinks and liquors)?
- |     |   |     |
|-----|---|-----|
| Yes | 1 | (9) |
| No  | ② |     |
| Ref | 7 |     |
| DK  | 8 |     |

SKIP TO E--

FOR EACH DRINK TYPE: *glasses of wine*  
*bottles or cans of beer*  
*mixed drinks or liquors* REPEAT QUESTIONS IN BOXED AREA.

Repeat question,  
starting with ID and  
going BACK 3 DAYS

Does [CASE NAME] ever drink [DRINK TYPE]?

On [DAY] how many [DRINK TYPE] did  
[HE/SHE] have?  
\*[If ID, probe for use before Focal Time.]

What was [CASE NAME]'s average WEEKLY consumption of [DRINK TYPE] in the last 6 months?

	Never Used	ID*	-1	-2	-3	Average weekly consumption
a. Glasses of wine	<input type="checkbox"/>	— — — (10)	— — — (13)	— — — (16)	— — — (19)	— — — 4 oz. glasses (22)
b. Bottles/cans of beer	<input type="checkbox"/>	— — — (25)	— — — (28)	— — — (31)	— — — (34)	— — — 12 oz. bottles (37)
c. Mixed drinks/liquors	<input type="checkbox"/>	— — — (40)	— — — (43)	— — — (46)	— — — (49)	— — — drinks (1oz liquor) (52)

IF ALCOHOL CONSUMED ON ID, -1, -2, OR -3, PROBE:

d. During this 4-day period, [HIS/HER] last alcohol-containing drink was on day [SPECIFY DAY].  
On that day, at what time of day did [HE/SHE] have [HIS/HER] LAST drink containing  
alcohol?

Time of day am 1 (55)  
pm 2  
dk 8



## TOBACCO USE

1. Has [CASE NAME] ever smoked cigarettes?

Yes 1 (5)  
 No 2  
 Ref 7  
 DK 8

SKIP TO 2 ←

a. At what age did [HE/SHE] first start smoking cigarettes?

7 6 (6)

b. Does [HE/SHE] still smoke cigarettes?

SKIP TO c ← Yes 1 Ref 7 (8)  
 No 2 DK 8

IF NO, PROBE:

How long has it been since [HE/SHE] last smoked?

\_\_\_\_ yrs. (9)

During the years [HE/SHE] smoked,

how many cigarettes would you say [HE/SHE] smoked in an average day? \_\_\_\_ cgs. (12)

SKIP TO d.

c.

Repeat question,  
 starting with ID and  
 going BACK 3 DAYS

Can you tell me, on [DAY] how many cigarettes did [HE/SHE] smoke?  
 \*If ID, probe for use before Focal Time.

How many cigarettes would you say [HE/SHE] normally smoked in an average day over the last 6 months?

	ID*	-1	-2	-3	Avg. daily cigarettes
Cigarettes	<u>0</u> <u>1</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u> cigarettes
	(15)	(18)	(21)	(24)	(27)

IF CIGARETTES USED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, [HIS/HER] last cigarette was on day [SPECIFY DAY],

On that day, at what time of day did [HE/SHE] have [HIS/HER] LAST cigarette?

05 : 59 am 1 (30)  
 Time of day pm 2  
 dk 8

d. Did [CASE NAME] use any nicotine patches (such as Nicoderm) or nicotine gum, (such as Nicorette) on ID or in the 2 weeks before ID?

Yes 1 No 2 Ref 7 (35)

2. Has [CASE NAME] ever smoked cigars?

Yes 1 (36)  
 No 2  
 Ref 7  
 DK 8

SKIP TO 3 ←

a. At what age did [HE/SHE] first start smoking cigars?

\_\_\_\_ (37)

b. Does [HE/SHE] still smoke cigars?

SKIP TO c ← Yes 1 Ref 7 (39)  
 No 2 DK 8

IF NO, PROBE:

How long has it been since [HE/SHE] last smoked?

\_\_\_\_ yrs. (40)

During the years [HE/SHE] smoked,

how many cigars would you say [HE/SHE] smoked in an average day? \_\_\_\_ cgs. (43)

SKIP TO d.

c.

Repeat question,  
 starting with ID and  
 going BACK 3 DAYS

Can you tell me, on [DAY] how many cigars did [HE/SHE] smoke?  
 \*If ID, probe for use before Focal Time.

How many cigars would you say [HE/SHE] normally smoked in an average day over the last 6 months?

	ID*	-1	-2	-3	Avg. daily cigars
Cigars	<u>0</u> <u>1</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u>	<u>2</u> <u>0</u> <u>0</u> cigars
	(46)	(49)	(52)	(55)	(58)

IF CIGARS USED ON ID, -1, -2, OR -3, PROBE:

During this 4-day period, [HIS/HER] last cigar was on day [SPECIFY DAY],

On that day, at what time of day did [HE/SHE] have [HIS/HER] LAST cigar?

\_\_\_\_ : \_\_\_\_ am 1 (61)  
 Time of day pm 2  
 dk 8

## INTERVIEWER OBSERVATIONS

[PLEASE COMPLETE IMMEDIATELY FOLLOWING INTERVIEW.]

1. Language ability of subject during interview:

No language problem	1	(5)
Has some difficulty speaking English	2	
Has great difficulty speaking English	3	

2. Language spoken by subject during interview:

English	1	(6)
Spanish	2	
Portuguese	3	
Italian	4	
Other	5	

SPECIFY:

3. Rate your confidence in the ability of the subject to give an accurate history:

Very confident	1	(7)
Fairly confident	2	
Confident	3	
Somewhat confident	4	
Little or no confidence	5	

4. Was anyone else present during the interview?

No	1	(8)
Spouse	2	
Child	3	
Other relative	4	
Friend	5	
Neighbor	6	
Other	7	

SPECIFY:

IF YES: How long were they present?

Entire interview	1	(9)
During first half only [i.e., sections A,B]	2	
During second half only	3	

5. Was the interview completed?

Yes; Interview completed with little (<1/10) or no missing information	1	(10)
Yes; Interview completed with considerable amount (>1/10) of missing information	2	
No: Interview terminated before completion	3	

IF INTERVIEW NOT COMPLETED: When did interview end?

Last page completed	_____	(11)
Last question completed	_____	(13)

6. Where was the interview conducted? Hospital 1 Rehab. center 2 Subject's home 3 Subject's office 4

IF OTHER, SPECIFY:

Friend/neighbor home 5 Other 6

7. Gender of proxy respondent

Female	1	
Male	2	(18)